

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the Claims

Claims 11-15 are cancelled presently, while claims 16-23 are added. New claims 16-22 are supported in the application as filed, *e.g.*, by original claims 1-7. Support for claim 23 is found in the specification at page 6, lines 7 and 8, *inter alia*. No new matter is added.

II. Objection to the Specification and Claims

In view of certain typographical errors, the examiner has objected to the specification and to claim 11 as well. Both are amended here to correct these inadvertent errors.

The examiner additionally urges a lack of clarity in the construction of claim 11. Solely to advance prosecution, claim 11 is revised in accord with a suggestion from the examiner on point. Accordingly, applicant requests withdrawal of these objections.

III. Claim Rejections under 35 U.S.C. 112, first paragraph

Claims 11-15 stand rejected for an alleged absence of adequate written-description support. In particular, the examiner alleges that the antibody concentration of “about 0.15 mg/ml” and an amino acid concentration of “about 12%” encompass concentrations that are somewhat less than 0.15 mg/ml and 12%, respectively.

Without acquiescing to the examiner’s contention, applicant has amended the claims to eliminate “about.” The examiner’s stated basis for rejection is inapposite to these claims, therefore, and applicant requests that the rejection be withdrawn.

IV. Claim Rejections under 35 U.S.C. 103

Claims 11-15 stand rejected as allegedly unpatentable over Borque *et al.*, *Eur. J. Clin. Chem. Clin. Biochem.* 1993 (12): 869-74, in view of U.S. Patents No. 4,362,531 (de Steenwinkel), No. 6,447,774 (Metzner), and No. 5,80,679 (Schmitdberger). According to the examiner, Borque discloses a turbidimetric immunoassay that meets applicant’s claim recitations but for the omissions of (i) a basic amino acid addition and (ii) specifying the antibody concentration employed in the claimed assay.

To bridge the gap represented by omissions (i) and (ii), the examiner combines Borque with de Steenwinkel, which discloses that an immunoassay may include “a chaotropic or chaotropic-like agent” to overcome “protein-protein interactions,” and Metzner, which teaches that “known chaotropic agents include arginine.” Office action at page 8, lines 5-13. Moreover, the examiner contends that, even though Schmidtberger “does not specifically teach adjusting the antibody concentration for the particular purpose mention, the reference clear establishes antibody concentration to be a result-effective variable.” *Id.*, at page 13, lines 1-3.

Yet, applicant’s claimed turbidimetric assay measures a plurality of lipoprotein(a) phenotypes that the primary reference explicitly discounts for contributing “only slightly to the size heterogeneity.” Borque at page 872, lines 15-17. Applicant discovered that using a high antibody concentration, as recited, along with the prescribed level of a chaotropic agent, circumvents the influence of isoform variation in measurements attributable to phenotypic variations. See specification at page 2, lines 24-26.

Thus, the claimed method detects numerous lipoprotein(a) phenotypes among individuals, which was not possible heretofore. Because no permutation of prior-art teachings, pursuant to Section 103, may contravene an express feature of the primary reference, see MPEP § 2143.01(VI), it necessarily follows the combination of references invoked by the examiner does not establish a *prima facie* case of obviousness.

Applicant also notes de Steenwinkel’s statement that “[c]haotropic agents are known per se and have a number of properties, among which is that of breaking or weakening non-covalent bonds such as hydrogen, electrostatic and hydrophobic bonds ...[and] they can reduce weak protein-protein interaction...” de Steenwinkel at column 2, lines 42-45. Conversely, the presently claimed assay teaches adding a high concentration of a chaotropic agent, such as arginine, in order to increase protein-protein interactions. According to the claimed method, in other words, increasing the chaotropic content increases the detectable interaction between the antibody and the various lipoprotein(a) phenotypes. Metzner and Schmidtberger make no suggestion along these lines that would have engendered an expectation of this result. For these reasons, too, the cited art fails to render the present claims obvious.

CONCLUSION

Applicants submit that the present application is in condition for allowance, and an early indication to that effect is requested. Examiner Marvich is invited to contact the undersigned directly should she feel that any item warrants further consideration.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then Applicant hereby petitions for such extension under 37 CFR § 1.136 and authorizes payment of the relevant fee(s) from the deposit account.